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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,564	11/01/2005	Trent Martin Woodruff	38871.33	1407

27683 7590 12/26/2006
HAYNES AND BOONE, LLP
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EXAMINER

KHANNA, HEMANT

ART UNIT	PAPER NUMBER
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1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/26/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/531,564	Applicant(s) WOODRUFF ET AL.	
	Examiner Hemant Khanna	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of claims 1-23 in the reply filed on November 22, 2006 is acknowledged. The amendment to claims 2-23 and the addition of claim 24, is acknowledged. The Examiner respectfully draws the Applicant's attention to an apparent discrepancy in the reply filed on November 22, 2006, in that the Examiner requested for identification of claims readable on the elected species in the Restriction filed on May 26, 2006, and while the Applicant states that all claims are generic to the species, it is believed that claims 4, 5, 15-16 do not read on the species "AcF-[OpdChaWR]". Claims 4-5 are drawn to a species wherein the "A" substituent is a substituted sulphonamide. It is believed that "A" in the elected species reads on NH-acyl. Claims 15-16 are drawn to the elected species in conjunction with other agents. Examiner respectfully submits a correction from the Applicant.

Applicant has elected the species of AcF-[OpdChaWR], and for a single inflammatory disease, the Applicant has elected the species of "Crohn's disease" Applicant's species has been found free of the prior art.

In accordance with Markush practice, should no prior art be found that anticipates or renders obvious the elected species, the search was extended to species encompassed by the base claim 1.

The above-mentioned species were also found free of the art. However the base claim 1 and all claims depending thereof are rejected under 35 USC 112, first paragraph as set forth below.

Claims 4-5, 15-16 are being rejoined as being drawn to nonelected species to which the search of the Markush claim was extended, there being an allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 22, 2006.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 recites the phrase "alleviate acute recurrences". Claim 17 recites the phrase "alleviate a primary occurrence". The phrases recited by the above-mentioned claims are indefinite, because it is not clear how the phrases differentiate the treatments of inflammatory bowel disease with respect to one another in view of their end-points that result from the administration of compound of formula 1, in the absence of an explicit definition of the phrases in the specification.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The specification, while being enabling for methods to treat inflammatory bowel disease mediated via the C5a receptor utilizing a C5a receptor antagonist, does not reasonably provide enablement for the methods to treat inflammatory bowel diseases mediated by all G-protein coupled receptors utilizing non-C5a receptor inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with claim 1.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in

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determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

Nature of the invention. The instant invention is to methods for treatment of inflammatory bowel disease mediated by a G protein-coupled receptor in subjects by administering an inhibitor represented by the compound of formula I.

Breadth of the claims. According to the language of the claims, the scope of the method of treatment can be extrapolated to inflammatory bowel disease mediated by any G-protein coupled receptor at all times in presence of the compound of formula I. The specification does not disclose a reasonable correlation between the treatment of inflammatory bowel disease mediated by receptors other than the C5a receptor.

State and un/predictability of the prior art. The claimed subject matter is lacking in predictability. While examples in the art exist for the treatment of inflammatory diseases, such as inflammatory bowel disease, mediated via the C5a receptor, no examples or models exist for the treatment of inflammatory bowel disease that are mediated by the broad class of G-protein coupled receptors, utilizing peptidomimetics, such as the compound of formula I. Specifically, Fairlie (1999) teaches methods of treatment of pathological conditions mediated via the G-protein coupled receptor, namely the C5a receptor (claims 19-26), by the administration of C5a receptor

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antagonists as represented by compounds of formula II (page 15). Further, Oostrum (1998) teach the administration of C5a antagonists for the treatment of inflammatory conditions, as in inflammatory bowel syndrome (column 10, lines 1-10). The teachings of the prior art are being interpreted by the fact that there was no option for treating inflammatory bowel disease by intercepting a G-protein coupled receptor other than the C5a receptor. In view of the above teachings a person of skill in the art would have no evidence that treatment of inflammatory bowel disease by a non-C5a receptor antagonist has any basis. It is presumed that the Applicant's intent is to treat inflammatory bowel diseases by inhibiting the activity of any G-protein coupled receptor with a peptidomimetic of formula I. Since the inflammatory bowel disease is limited to being mediated by the C5a receptor, the inhibition of all G-protein coupled receptors, is not enabled.

Working examples. Although examples are disclosed in the specification that demonstrate receptor binding assays and the *in vivo* activity of AcF-[OpdChaWR] in a rat model of inflammatory bowel disease, there is no evidence for the intended treatment of inflammatory bowel disease comprising receptor antagonists non-specific to the G-protein coupled receptors that mediate inflammatory bowel disease.

Guidance in the specification. The specification provides little guidance regarding practice of the claimed methods to extrapolate the methods of treating inflammatory bowel disease comprising the administration of an any G-protein coupled receptor antagonist of formula I from the method of treating inflammatory bowel disease comprising the administration of a C5a specific receptor antagonist as represented by

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formula I. There is a lack of predictability in the art regarding the use of the claimed antagonist to antagonize receptors which are not C5a G-protein coupled receptors.

Amount of experimentation necessary. Given the unpredictability of the art in view of the use of the antagonist represented by formula I to treat inflammatory bowel disease by antagonizing any G-protein coupled receptor, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate with the scope of the claim. Although the applicants have identified an interesting method of treatment of inflammatory bowel disease, but essentially all of the work required to extrapolate the antagonism of any G-protein coupled receptor needs to be further undertaken.

Relative Skill of those skilled in the art. In view of the discussion of each of the preceding seven factors the level of skill in this art is high and is at least that of a Ph.D. with several years of experience in the art. As the cited art would point to, even with a level of skill in the art that is Ph.D. predictability of the results is not invariable.

In consideration of each of the factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Allowable Subject Matter

The species of antagonist represented by AcF-[OpdChaWR], and the inflammatory bowel disease represented by Crohn's disease are free of the prior art.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant Khanna whose telephone number is (571) 272-9045. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Hemant Khanna
December 14, 2006



B. DELL CHISM
PRIMARY EXAMINER